Message Text

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OES/APT/BMP FOR WILLIAM WALSH

DEPT PASS TO DHEW/FDA

E.O. 11652: N/A TAGS: TBIO, JA

SUBJECT: SMON TRIAL

- 1. SUMMARY: TOKYO DISTRICT COURT WAS SECOND FOLLOWING NAKAZAWA DISTRICT COURT TO CONCLUDE HEARINGS IN SMON LAWSUIT JULY 19, PAVING WAY FOR OUT-OF-COURT SETTLEMENT, FOR THOSE PLAINTIFFS AND DEFENDANTS DESIRING SETTLEMENT, AND COURT VERDICT FOR THOSE PLAINTIFFS DEMANDING COURT JUDGMENT, END OF SUMMARY.
- 2. GOVERNMENT AND THREE DRUG FIRMS IN THEIR FINAL ARGUMENTS DENIED LEGAL RESPONSIBILITY FOR THE OUTBREAK OF SMON "DISEASE" AS TOKYO DISTRICT COURT CONCLUDED ITS SIX-YEAR-OLD TRIAL JULY 19 IN THE 90 BILLION YEN DAMAGE SUIT FILED BY ABOUT 2,000 PATIENTS OR THEIR RELATIVES.

 SMON (SUBACUTE MYELO-OPTICO NEUROPATHY) IS A NERVOUS SYSTEM AILMENT LINKED TO QUINFORM DRUG USED IN TREATING INTESTINAL DISORDERS.
- 3. STATE AND TWO OF THE DRUG FIRMS--TAKEDA CHEMICAL INDUSTRIES AND CIBA-GEIGY (JAPAN)--EARLIER EXPRESSED UNCLASSIFIED

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THEIR WILLINGNESS TO ACCEPT OUT-OF-COURT SETTLEMENT PROPOSAL MADE BY PRESIDING JUDGE KABE. THE REMAINING DEFENDANT, TANABE SEIYAKU, IS REFUSING TO FOLLOW SUIT. ABOUT 80 PERCENT OF PLANTIFFS FAVOR OUT-OF-COURT SETTLEMENT WHILE REMAINING PLAINTIFFS ARE RESOLVED TO SEEK COURT RULING IN ORDER TO CLARIFY THE DEFENDANTS' LEGAL AND SOCIAL RESPONSIBILITIES.

- 4. AFTER HEARING FINAL ARGUMENTS BY ALL DEFENDANTS, JUDGE KABE DECLARED HE HAD WOUND UP HEARING FOR 163 OUT OF 2,000 PLAINTIFFS. THEY BELONG TO FIRST GROUP OF PLAINTIFFS WHO FILED A DAMAGE SUIT WITH COURT IN 1971. COURT IS EXPECTED TO CONCLUDE HEARINGS FOR REMAINING PLAINTIFFS ONE AFTER ANOTHER. COURT RULING IS DUE TO BE HANDED DOWN BY END OF THIS YEAR, AT LEAST, FOR MINORITY GROUP OF PLAINTIFFS SEEKING COURT JUDGMENT ON THEIR SUIT. ON THE OTHER HAND, FULL-FLEDGED NEGOTIATIONS WILL BE STARTED SOON BETWEEN THE DEFENDANTS, EXCLUDING TANABE, AND THE MAJORITY GROUP OF PLAINTIFFS CONCERNING COMPENSATION.
- 5. VERDICT IS EXPECTED TO ASSAIL THE DRUG FIRMS INVOLVED NOT ONLY FOR THEIR FAILURE TO MAKE PUBLIC SIDE-EFFECTS OF THE DRUG CONCERNED BUT FOR THEIR EXCESSIVE COMMERCIALISM TO ENCOURAGE CONSUMPTION OF THE DRUG AND TO PROMOTE ITS SALES. IT ALSO IS EXPECTED TO CHARGE GOVERNMENT WITH NEGLIGENCE IN NOT TAKING ACTION TO DETERMINE THE EFFICACY AND SAFETY OF THE DRUG.
- 6. MAJOR PROBLEM THAT CANNOT BE SOLVED EITHER BY COURT RULING OR BY OUT-OF-COURT SETTLEMENT IS HOW TO PROVIDE RELIEF TO THOSE PATIENTS WHO HAVE NOT FILED LINCLASSIFIED.

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LAWSUIT. ACCORDING TO MHW SURVEY, THERE ARE ABOUT 11,000 LATENT PATIENTS THROUGHOUT JAPAN. ANOTHER ESTIMATE PUTS THE NUMBER AT AS MANY AS 20,000. OF THESE ONLY ABOUT 3,600 HAVE FILED SUIT WITH DISTRICT COURTS THROUGHOUT THE COUNTRY.

7. EMBASSY HAS NOT REPORTED ON SMON CONTROVERSY FOR SOME TIME BECAUSE OF THE UNCERTAINTIES OF LITIGATION IN PROGRESS. FOLLOWING IS SMON CHRONOLOGY: IN 1955--SPORADIC CASES OF SMON REPORTED THROUGHOUT THE COUNTRY; SEPT. 1969---SMON RESEARCH PANEL ORGANIZED AT MHW; SEPT. 1970--MHW BANNED ALE AND USE OF QUINOFORM; MAY 1971--SMON PATIENTS FILED DAMAGE SUIT WITH TOKYO DISTRICT COURT; JUNE 1973--FIRST ORAL PROCEEDINGS AT TOKYO DISTRICT COURT; JUNE 1976--THREE DRUG FIRMS INVOLVED IN CASE EXPRESSED WILLINGNESS TO SETTLE CASE OUT OF COURT; PROPOSAL REJECTED BY PLAINTIFFS; SEPT. 1976--PRESIDING JUDGE KABE RECOMMENDED OUT-OF-COURT SETTLEMENT. PLAINTIFFS DIVIDED INTO TWO GROUPS, ONE FAVORING SETTLEMENT AND THE OTHER DEMANING COURT RULING: JAN. 1977--TOKYO DISTRICT COURT OFFERED FIRST SETTLEMENT PLAN; APRIL 1977--TOKYO DISTRICT COURT OFFERED

SECOND SETTLEMENT PLAN; MAY 1977-HEARINGS CONCLUDED AT KANAZAWA DISTRICT COURT; JUNE 1977--GOVERNMENT ACCEPTED BROAD OUTLINE OF PROPOSAL FOR OUT-OF-COURT SETTLEMENT; JUNE 1977--TAKEDA AND CIBA-GEIGI (JAPAN) ACCEPTED PROPOSAL FOR SETTLEMENT; JULY 1977--PLAINTIFFS FAVORING SETTLEMENT ACCEPTED PROPOSAL BUT THOSE DEMANDING COURT RULING REJECTED PROPOSAL; JULY 18, 1977--PLAINTIFFS PRESENTED FINAL ARGUMENTS; JULY 1 19--DEFENDANTS PRESENTED FINAL ARGUMENTS; HEARINGS CONCLUUDED.

8. COMMENT: THE SMON CASE IS AN INTERESTING ONE FROM SEVERAL POINTS OF VIEW. IT IS ANOTHER IN THE SERIES OF RECENT CONTROVERSIES PITTING A RELATIVELY LARGE UNCLASSIFIED

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SEGMENT OF THE CONSUMER PUBLIC AGAINST THE ESTABLISHMENT IN AN ATTEMPT TO CLAIM DAMAGES FOR HARM DONE. IT IS AT THE SAME TIME A CLASSICAL CASE IN JAPANESE JURISPRUDENCE, TAKING AN INORDINATE LENGTH OF TIME FOR THE LEGAL SYSTEM TO BRING THE CASE TO A CLOSE ATTEMPTING TO FORCE PLAINTIFFS AND DEFENDANTS TO REACH AN OUT-OF-COURT SETTLEMENT RATHER THAN BY THE COURT MAKING A PRECEDENTIAL DECISION. END COMMENT. MANSFIELD

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